

AFFIDAVIT UNDER RULE 1.131 AND 1.132
IN SUPPORT OF U.S. APPL. SER. NO. 10/734,812

I, A. Peter Jardine, do hereby declare that the following statements are true, understanding that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

I am a citizen of the United States and I reside at 1731 Hendrix Avenue, Thousand Oaks, State of California, County of Ventura.

I am the President of Shape Change Technologies, which develops processing and products exhibiting a two-way shape memory effect. I have been working in the field of shape change materials for 24 years. I received a B.S. degree in Physics from St. Andrews University (Scotland) and a Ph.D. in Materials Physics from the University of Bristol (England). I was a professor at the State University of New York, Stony Brook for 5 years prior to working at Northrop Grumman Corporation as a Senior Technical Specialist in the field of active materials.

I am the inventor in the above-identified patent application. I invented, prior to November 6, 2002 in the United States, the subject matter corresponding to the invention broadly disclosed and claimed in the above-identified patent application and disclosed but unclaimed in U.S. Pat. No. 6,775,046 ("the '046 Patent).

With regard to the '046 Patent, the disclosure suggests that other metal alloys, such as ternary Ni:Ti:X and binary Au:Cu, also exhibit shape memory effect. The examiner extrapolates this disclosure to indicate that it would be obvious to use Au:Cu and additional shape memory alloys other than Ni:Ti alloys in a process the same as that disclosed for binary Ni:Ti to produce a two-way shape memory alloy. However, based on information and belief, after having

developed binary, ternary and higher order shape memory effect devices with two-way shape memory effect and after numerous experiments, including experiments and calculations ruling out alloy systems from contention as suitable for two-way shape memory effect, it is my opinion that Au:Cu is not amenable to the two-way shape memory effect, using any process that varies the temperature of the target. Although it might be obvious to try Au:Cu based on the disclosure of the '046 Patent, any thin film made from such an alloy would not operate as a two-way shape memory effect device. A person of ordinary skill in the art would not be able to produce a device having two-way shape memory effect using a Au:Cu target. Furthermore, using the same process parameters that were disclosed previously for Ni:Ti does not necessarily produce a shape memory effect device with other shape memory alloy targets.

U.S. Pat. Publ. No. 2002/0043456 to Bement is cited "simply to show that gold-cadmium, copper-zinc-aluminum and copper-nickel-aluminum compositions are conventional shape memory alloy compositions in the art." However, Bement states in paragraph [0026] that a "...multitude of different compositions of SMA may be used, including, but not limited to, the following: gold-cadmium, silver-cadmium, copper-aluminum-nickle, copper-tin, copper-zinc, copper-zinc-aluminum, indium-titanium, indium-thalium, iron-platinum, nickel-aluminum, iron-manganese-silicon, manganese-copper, and nickel-titanium." In the same paragraph, Bement goes on to state that "...each of the aforementioned SMAs may comprise different percentages of each component metal." There are a "multitude of different compositions" of shape memory alloys from which an ordinary practitioner must choose.

By multiplying the multitude of different compositions and the variety of different percentages of each component metal, the number of shape memory alloy compositions to try becomes infinite. Furthermore, as stated in the specification, processing conditions, such as specific ranges of target temperature, processing temperatures of the wafer, and vacuum pressures during sputter deposition are needed to make two-way shape memory effect devices. Thus, even if it is obvious to try other shape memory alloys, besides Ni:Ti, the infinite variety of shape memory alloys, percentages of component metal, and combinations of processing conditions requires undue experimentation by a routiner in the art. As the references that teach two-way shape memory devices are limited only to Ni:Ti, and alloys thereof, as an operable system, a person of ordinary skill in the art would not have sufficient expectations of success in

developing new two-way shape memory effect processes with new alloys without undue experimentation. In addition, the equipment required to prepare a Ni:Ti thin-film, two-way shape memory device is very expensive and must be substantially customized to allow for controlling the important processing conditions. Furthermore, each experiment is a complicated and time-consuming task that takes laboratory time and talented technicians to prepare the targets, substrates and high vacuum chamber, sputter deposit the device under the correct processing conditions, further processing of the sample to etch at least a portion of the thin film from the substrate, preparing a method of heating the thin film or activating the shape memory effect in some other manner, and verifying that shape memory effect, if any, is repeatable and useful. Thus, undue experimentation would be necessary to determine the specific shape memory alloys and processing conditions disclosed and claimed in the above-referenced application.

The Examiner suggests that it would have been obvious to a person of ordinary skill in the art of shape memory effect actuators to make an actuator of any shape using the process disclosed in U.S. Publ. No. 2002/0043456. As an expert in this field, I can attest that it was not obvious to design a process that allows a thin film of shape memory alloy that is deposited on a non-planar surface to have a compositional gradient that achieves a two-way shape memory effect. Depositing a thin film on a planar surface for a small device is accomplished merely by varying the temperature of the target within a defined temperature range during sputter deposition with a fixed target and fixed substrate. However, the thin film composition also changes based on the distance from the target to the scaffold structure of a non-planar surface. Therefore, depositing a uniform thin film that exhibits two-way shape memory effect on a larger surface or three-dimensional surfaces, such as a curved surface, surfaces of cylinders and annuli, complex stents, or porous scaffolds required the development of new processes that accounted for the effects of distances from the target and curvature on the compositional gradient through the thickness of the film.

These developments were not obvious to any practitioner at the time that the present application was filed. Both the choice of alloy and processing conditions has an effect on the rotation and diffusion of ions that permits the slight changes in the sputtering plume to form a two-way shape memory effect thin film on a non-planar surface through accretion, while the temperature of the target is varied. For alloys relying on titanium as one of the elements in the

shape change alloy, it proved to be necessary to move the relative position of the three-dimensional scaffold structure in relation to the target in such a way as to provide an active region of the film with the desired, two-way shape memory effect, such as by rotation, because the distance to the target has a significant effect on the composition of titanium in the thin film even if very high vacuum pressures are drawn in the vacuum chamber. The desire to avoid costly and difficult to design and maintain processes that require relative movement between the three-dimensional substrate scaffold and the target led to development of new two-way shape memory alloys that use elements that are less sensitive to impurities in the vacuum chamber and distances between the target and the surface of the substrate scaffold. Development of these new alloys and processes required much work, as outlined in this declaration. Both movable scaffolds and development of new alloys and processing conditions have led to major advances in the ability to create useful three-dimensional shape change memory devices, such as fenestrated tubular elements, porous foams and dimpled spherical structures, exhibiting shape memory effect, which were not possible to form previously.

With regard to development of new alloys, Prof. Carman, Ken Ho, and I diligently actually reduced to practice in the United States, Ti:Ni thin film shape memory effect devices in the above-identified patent application on or prior to November 6, 2002, the filing date of the above-referenced patent application, only after years of efforts to determine the correct composition and processing parameters. The reduction to practice required the following steps to be completed prior to successfully determining the appropriate processing ranges:

- a. The ranges that we considered were from 47.5% Ni-Ti to 53.% Ni-Ti.
- b. Each of the alloy systems that was examined required a target to be fabricated, each at a considerable cost in time and money. In each alloy composition, specific processing parameters needed to be identified that would generate the correct SME or SE response. This process was extremely costly and time consuming. Finally, we determined that one composition worked for the SME material (47.5 at.% Ni-Ti) and one worked for the SE material (50.0at% Ni-Ti), using practical processing conditions. The amount of detail and time involved in establishing a proper protocol to synthesize the materials is great, and the range of suitable processing parameters

and distances to the target material are narrow. Thus, more often than not, experiments failed to produce a practical two-way shape memory effect thin film.

- c. Furthermore, each new alloy system requires the use of a different combination of target temperature, processing temperature of the wafer, distance from the target to the wafer and vacuum pressure ranges during processing in order to successfully manufacture two-way shape memory alloy devices, requiring months of work. This depends not only on the base alloy, but also on the element or elements chosen for X in ternary and higher order alloys, greatly increasing the complexity. Development of new shape memory alloys for two-way shape memory effect devices requires tireless effort and experimentation to synthesize and characterize materials in the correct processing range to produce practical two-way shape memory effect devices. Ternary and higher order alloys require even more work in selecting the compositional ranges for the higher order elements.
- d. The nearly limitless choice of alloys, chemistries and processing conditions makes selection of the right alloy constituents and process variables an exceedingly difficult task for even an expert in the field, which has necessitated research, including experimentation and calculations, to determine the desired ranges of the various processing variables.
- e. The processing variables for NiTi were not transferable to other alloy systems of ternary and higher order.

Surprisingly, the newly-disclosed, shape memory alloys produce two-way shape memory effect with less stringent vacuum requirements than required for NiTi shape memory alloys. This makes the manufacturing process less costly and is expected to allow larger samples and three-dimensional samples of two-way shape memory effect thin films than could have been produced using NiTi alloys. Furthermore, relative movement between the target and the scaffold substrates may not be required that would have been required with use of NiTi alloys. These improvements provide a significant, non-obvious commercial advantage over NiTi alloys. For example, larger target and device sizes and the development of manufacturable, macroscopic three-dimensional

elements, such as tubular thin film coatings on permanent or sacrificial scaffold materials of any arbitrary three dimensional shape, including fenestrated tubular elements, domes and dimpled spherical structures as well as porous foam structures, may be accomplished that could not be accomplished with Ni:Ti binary shape memory alloy.

Further the declarant saith not.



Date: Dec 7 2004

Signature: _____
A. Peter Jardine